



PRODUCT LIABILITY LITIGATION UPDATE

June 2026

Federal Rule 16.1: How It Changes Early Defense Strategy in Product Liability Multidistrict Litigation

Key Notes:

- Federal Rule of Civil Procedure 16.1, effective December 1, 2025, is the first federal rule directed specifically at multidistrict litigation, establishing an initial management conference, a joint pre-conference report, and an initial management order.
- For product liability defendants, the rule creates new leverage to seek early claim substantiation – through plaintiff fact sheets and census mechanisms – and to resolve unsupported claims before costly merits discovery begins.
- The Advisory Committee Notes endorse addressing threshold issues early – including general causation, preemption, and Rule 702 / Daubert challenges – supporting phased, sequenced discovery that can resolve large categories of claims before extensive merits work.
- To capitalize, defense counsel should arrive at the initial conference with concrete proposals on fact sheets, discovery sequencing and threshold motions, citing the Notes’ support for expedited resolution of unsubstantiated claims.

Federal Rule of Civil Procedure 16.1, which took effect on December 1, 2025, is the first federal rule specifically directed at multidistrict litigation (MDL). For companies defending product liability MDLs, the rule offers new opportunities to seek early claim substantiation, resolve threshold legal issues, and streamline litigation before costly merits discovery begins.

Executive Summary

Rule 16.1 establishes a formal framework for early MDL case management. The rule directs courts to hold an initial management conference, requires the parties to prepare a

pre-conference report, and contemplates an initial management order addressing key procedural and substantive issues.

MDLs now account for approximately 50% of all pending federal civil actions, with more than 200,000 cases pending as of June 2026. Product liability cases comprise more than 90% of all MDL proceedings. Before Rule 16.1, no Federal Rule specifically governed MDL case management.

For defendants, the rule provides a new basis to seek early claim vetting and the staged resolution of threshold issues. The Advisory Committee Notes (Notes) acknowledge that “some claims and defenses have been asserted without the inquiry called for by Rule 11(b)” and endorse mechanisms to identify and resolve unsupported claims early.

What Rule 16.1 Requires

Rule 16.1 establishes a three-step procedural framework that applies after the Judicial Panel on Multidistrict Litigation transfers actions to a transferee court:

Initial Management Conference

Under Rule 16.1(a), the transferee court “should schedule an initial management conference to develop an initial plan for orderly pretrial activity in the MDL proceedings.” Although the rule uses “should” rather than “must,” the Notes make clear that courts are expected to hold these conferences routinely.

Pre-Conference Report

Under Rule 16.1(b), the transferee court should order the parties to meet and confer and submit a joint report addressing the following topics:

Organizational Matters (Rule 16.1(b)(2))

- Whether leadership counsel should be appointed;
- Previously entered orders that should be vacated or modified;
- A schedule for additional conferences;
- How to manage direct filing of new actions in the transferee court; and
- Whether related actions filed in other courts should be addressed.

Substantive Matters (Rule 16.1(b)(3))

- Whether consolidated pleadings should be prepared;
- How and when parties will exchange information about factual bases for claims and defenses;
- Discovery planning, including difficult issues likely to arise;
- Likely pretrial motions;
- Measures to facilitate resolution of claims or defenses;
- Referral to a magistrate judge or special master; and
- The principal factual and legal issues in the proceedings.

Initial Management Order

Under Rule 16.1(c), the court should enter an initial management order addressing the matters identified in the report and establishing timelines for threshold motions, discovery sequencing, and claim-substantiation requirements.

Early Vetting of Claims: The Key Defense Opportunity

The most consequential provision of Rule 16.1 for defense strategy is the requirement that the pre-conference report address “how and when parties will exchange information about factual bases for claims and defenses.” The Notes make clear that this provision is intended to facilitate the early identification of unsubstantiated claims:

“Experience has shown that in many cases an early exchange of information about the factual bases for claims and defenses can facilitate efficient management.”

The Notes further identify specific mechanisms courts may use to accomplish this goal:

Plaintiff Fact Sheets

Courts may require plaintiffs to complete detailed fact sheets providing information about product exposure, injury, medical history, and causation. The Advisory Committee specifically endorses “fact sheets” as a method of early information exchange. Defense counsel should consider advocating for fact sheets requiring plaintiffs to identify:

- The specific product(s) used and duration of use;
- Medical diagnoses and treating physician(s);
- Proof of purchase or product use;
- The timeline of the alleged injury; and
- Alternative exposures or risk factors.

Census Mechanisms

The Advisory Committee also endorses using a “census” approach to survey claims. A census helps the court and parties understand the composition of the MDL docket, including identifying how many plaintiffs assert particular injuries, products involved, and potential jurisdictional issues. For defendants, a census provides early visibility into the universe of claims and supports more targeted motion practice.

Expedited Resolution of Unsupported Claims

Perhaps most importantly, the Notes state that “after taking account of whether the party whose claim or defense is involved has reasonable access to needed information, the court may find it appropriate to employ expedited methods to resolve claims or defenses not supported after the required information exchange.”

This language expressly authorizes courts to consider expedited procedures for resolving claims that plaintiffs cannot substantiate through early disclosure requirements.

Application to Product Liability MDLs

With approximately 90% of MDL proceedings involving product liability claims, including large dockets involving talcum powder (68,000+ cases), hernia mesh, hair relaxers, and social media addiction, the rule's early-vetting framework has significant implications.

General Causation as a Threshold Issue

The Notes identify "general causation" as one of the issues "that should be addressed early in the proceeding." Defense counsel can rely on this language to advocate for sequenced discovery that addresses general causation before extensive individual merits discovery begins.

Recent MDL experience demonstrates the effectiveness of this approach. In the Zantac and Paraquat proceedings, courts excluded plaintiffs' general causation experts under Rule 702, resulting in summary judgment on broad categories of claims.

Preemption

The Notes also identify "preemption" as a threshold issue that may warrant early resolution. In product liability MDLs involving FDA-regulated products, including pharmaceuticals, medical devices, and biologics, preemption can eliminate entire categories of state-law claims.

Rule 16.1's emphasis on identifying the "principal factual and legal issues" early provides defendants with a strong basis to seek preemption briefing before engaging in extensive merits discovery.

Rule 702 and Daubert Gatekeeping

Amended Rule 702, which became effective on December 1, 2023, clarifies that the proponent of expert testimony bears the burden of establishing reliability by a preponderance of the evidence.

Combined with Rule 16.1's sequencing framework, defense counsel may advocate for early Daubert proceedings on general causation before bellwether selection or extensive case-specific discovery. The interaction between Rules 16.1

and 702 is potentially significant: where a court addresses general causation early and rigorously applies Rule 702, thousands of claims could be resolved through a single evidentiary ruling.

Sequenced Discovery

Rule 16.1 requires the parties to address "discovery including difficult issues" in the pre-conference report. Defense counsel can consider proposing a phased discovery structured as follows:

Phase 1: Plaintiff fact sheets and census procedures to substantiate claims;

Phase 2: Threshold legal and scientific issues, including preemption, jurisdiction, and general causation; and

Phase 3: Focused merits discovery for claims that survive threshold challenges.

Practical Recommendations for Defense Counsel

Based on the rule's text and the Advisory Committee Notes, defense counsel should consider the following:

- **Arrive with concrete proposals.** Prepare detailed written proposals addressing plaintiff fact sheets, discovery sequencing, and threshold motion practice. Courts are more likely to adopt practical, fully developed case-management proposals.
- **Cite the Advisory Committee Notes directly.** Highlight language authorizing "expedited methods to resolve claims or defenses not supported after the required information exchange."
- **Propose robust fact-sheet requirements.** Tailor fact sheets to the specific MDL and require proof of product purchase, use, exposure, and injury, with clear deadlines and consequences for noncompliance (dismissal without prejudice).
- **Identify threshold issues early.** Flag preemption, jurisdictional challenges, and general causation issues in the pre-conference report and request that they be addressed before merits discovery.
- **Coordinate with Rule 702.** Where general causation is disputed, propose a schedule that aligns early information exchange with Daubert briefing and expert challenges.

- **Leverage Rule 16.1 in existing MDLs.** Even in proceedings that predate the rule, courts may be receptive to adopting aspects of the framework prospectively.
- **Anticipate plaintiffs' objections.** Plaintiffs may argue that early vetting is burdensome or one-sided. Defendants can point to Rule 16.1 and Rule 11(b) as support for requiring early substantiation of claims.
- **Document compliance and non-compliance.** Track responses to fact-sheet and census requirements and seek appropriate relief when plaintiffs fail to provide required information.

Conclusion

Rule 16.1 marks a significant development in MDL practice. Combined with the Advisory Committee's emphasis on addressing unsupported claims, the rule provides defendants with a stronger basis to seek early claim substantiation and the efficient resolution of threshold legal and scientific issues.

Defense counsel who engage proactively—by presenting practical case-management proposals, advocating for early information exchange, and coordinating threshold challenges with Rule 702 motions—will be best positioned to shape MDL proceedings and reduce the costs associated with unsupported claims.

FOR MORE INFORMATION

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